UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,898	07/05/2001	Harm M. Deckers	034547-0104	3117

22428 7590 07/05/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
PAK, YONG D	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,898	DECKERS ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/19/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

C.O.D

DETAILED ACTION

This application is a CIP of 09/577,147, now issued as U.S. Patent No. 6,372,234.

The amendment filed on February 28, 2005, amending claims 14, 18 and 29, has been entered.

Claims 14-18 and 29 are pending.

Response to Arguments

Applicant's amendment and arguments filed on February 28, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

As previously stated, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

The parent application, 09/448,755, does not disclose a method of preparing an emulsion formulation by using cells transformed with polynucleotides encoding a thioredoxin or thioredoxin reductase, which is claimed in the instant application. 09/448,755 describes a method of preparing an emulsion formulation by using cells transformed with polynucleotides encoding a fusion protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "intact oil bodies". It is not clear to the Examiner either from the specification or form the claims as to what applicants mean by the above phrase. As applicants have not provided a definition for the above phrase, the metes

and bounds of the phrase in the context of the above claim are not clear to the Examiner.

Claims 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "intact oil bodies". It is unclear to the Examiner how "intact oil bodies" are prepared or how "intact oil bodies" are separated from non "intact oil bodies". In the context of the above, Examiner takes the position that these claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are: steps in preparing only "intact oil bodies" or separating "intact oil bodies" from non "intact oil bodies".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-18 and 29 are drawn to a method of preparing an emulsion formulation by isolating oil bodies comprising a fusion protein and washing said oil bodies to obtain a washed oil body preparation comprise of "intact oil bodies". However, washing said oil bodies isolated from cells to obtain an oil preparation comprising of "intact oil bodies" were not described in the application as originally filed nor in any of its parent applications. The specification as filed contains disclosure of a washing oil bodies isolated from ground plant seeds to obtain substantially "intact oil bodies". Obtaining oil bodies derived from recombinant cells was not describe. Therefore, claims 14-18 and 29 contain new matter.

Given this lack of description of obtaining intact oil bodies from washing oil bodies derived from a recombinant cell, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 14-18 and 19 at the time of filing of the instant application.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov <http://www.uspto.gov>.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16, 18 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Voultoury et al.

Claims 14-16 and 18 are drawn to a method of making an emulsion comprising a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a thioredoxin or thioredoxin reductase which is further linked to a polynucleotide capable of terminating transcription in a plant cell, wherein oil bodies comprising the fusion protein is isolated. Claim 29 limits claim 14 in that the thioredoxin or thioredoxin reductase of the emulsion reduces a target.

Moloney et al. (WO 93/21320 – form PTO-892) teach method of making a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell, wherein oil bodies comprising the fusion protein is isolated (pages 2, 8-9, 20, 21 and 26). Moloney et al. also teaches that the fusion protein can be contacted with a substrate of the heterologous protein, leaving out extra steps such as a cleavage and purification step (page 21). Moloney et al. also teaches that oleosins provide a means for separation of foreign proteins from plant derived materials (page 2).

The difference between the reference of et al. and the instant invention is that the reference of Moloney et al. does not teach a method of emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase.

Wieles et al. (form PTO-892) teaches polynucleotides encoding a thioredoxin and thioredoxin reductase (abstract and pages 921-922). Wieles et al. also teaches that thioredoxin and thioredoxin reductase is involved in redox regulation (abstract). Thioredoxin and thioredoxin reductase are well established proteins in the art (see NiceZyme: EC 1.8.1.9 – form PTO-892).

Voultoury et al. (EP 0 680 751 A1 – form PTO-892) teach a method of formulating emulsions comprising oil body proteins (pages 2-5 and see corresponding U.S. Patent No. 5,683,740 – PTO-1449 - for translation into English). Voultoury et al.

teaches that emulsions can be used in a variety of applications, such as in pharmaceutical compositions.

Combining the teachings of Moloney et al., Wieles et al. and Vouloutry, it would have been obvious to one having ordinary skill in the art use thioredoxin or thioredoxin reductase of Wieles et al. in the fusion protein of taught by Moloney et al. and formulate the fusion protein into an emulsion. One of ordinary skill in the art would have been motivated to use thioredoxin or thioredoxin reductase as the heterologous protein in the fusion protein of Moloney et al. since thioredoxin and thioredoxin reductases plan important roles in redox regulation. One of ordinary skill in the art would have had a reasonable expectation of success of making the fusion protein and isolating the fusion protein since Monoley et al. teaches fusion proteins comprising oleosins can be successfully separated from plant derived materials. One of ordinary skill in the art would have been motivated to formulate a fusion protein comprising an oil body protein and a thioredoxin or thioredoxin reductase to stabilize the thioredoxin or thioredoxin reductase in order to use it to reduce their substrates without adding steps in cleaving the oleosin from thioredoxin or thioredoxin reductase. One of ordinary skill in the art would have had a reasonable expection of success in making the emulsion since Voultoury et al. successfully teaches an emulsion comprising oleosins.

Therefore, the above references render claims 14-16, 18 and 29 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that Mononey et al. and Wieles et al. fail to disclose

formulating a emulsion formulation comprising a fusion protein comprising a thioredoxin or thioredoxin reductase. This is true, however, Voultoury et al. discloses formulating an emulsion. Further, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants also argue that Voultoury et al. discloses a method for preparing lipid vesicles from crushed seeds, wherein the oil bodies are substantially destroyed. While this may be true, Voultoury et al. is relied upon for its disclosure on a method of preparing an emulsion comprising oil bodies (step (e) of claim 14), upon lysing or disruption of cells comprising the fusion protein.

Also, applicants state the oil bodies of Volutoury et al. are "substantially" destroyed, which indicates that some oil bodies are still intact and the claims do not recite any limitations on the degree of intact oil bodies.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Voultoury et al. as applied to claims 14-16, 18 and 29 above, and further in view of Hildebrand et al.

Claim 17 is drawn to a method making an emulsion comprising a fusion protein, wherein the fusion protein is expressed in safflower cells.

The references of Moloney et al., Wieles et al. and Voultoury et al.in combination teach a method of making an emulsion comprising a fusion protein comprising a thioreodixn or thioredoxin reductase and an oleosin, as discussed above.

The difference between the combined references and the instant invention is that the combined references do not teach the method using a safflower cell for the expression of the fusion protein.

Hildebrand et al. (EP 0 550 162 A1 – form PTO-892) teach a method of expressing heterologous proteins in safflower cells (page 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to express the fusion protein in safflower cells. The motivation of expressing the fusion protein in safflower cells is to express the oil body protein in an oil-bearing crop. One of ordinary skill in the art would have had a reasonable expectation of success since expression of fusion proteins in plant cells such as safflower cells are performed routinely in the art.

Therefore, the above references render claim 17 is *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants also argue that Voultoury et al. discloses a method for preparing lipid vesicles from crushed seeds, wherein the oil bodies are substantially destroyed. While this may be true, Voultoury et al. is relied upon for its disclosure on a method of

preparing an emulsion comprising oil bodies (step (e) of claim 14), upon lysing or disruption of cells comprising the fusion protein.

Also, applicants state the oil bodies of Volutoury et al. are "substantially" destroyed, which indicates that some oil bodies are still intact and the claims do not recite any limitations on the degree of intact oil bodies.

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600